



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/814,777

03/30/2004

Yenamandra Venkateswarlu

03108/0201123-US0

4938

7278

7590

06/05/2009

DARBY & DARBY P.C.

P.O. BOX 770

Church Street Station

New York, NY 10008-0770

EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

06/05/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,777	<b>Applicant(s)</b> VENKATESWARLU ET AL.	
	<b>Examiner</b> Rita J. Desai	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 3-10, 12, 15 and 24-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11, 13, 14, 20, 21, 23, 48-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1625

### DETAILED ACTION

Claims 1,2,11 , 13, 14, 20, 21, 23, 48-52 are in the elected group.

Claims 3-10,12,15-10, 24-47 are withdrawn.

Response to the arguments:-

Applicants argue that one of skill in the art would know how to make the different compounds such as the anhydrides, amides, amines. Applicants claim is drawn to an isolated compound.

The process of isolating the compound as given in the specifications does not include making these compounds. The starting materials and the process is also not given. The references given by the applicants shows mechanisms drawn to tautomers , =O and -NH groups . Applicants claims are drawn to compounds which are substituted at

positions 1, 4, 5, and 8 are optionally substituted with halogen, amine, amino, imino, carboxylic acid or amide,

There are no examples made. The specifications has one exaction process on pages 11 and 12 and uses a limited number of reagents. These are at different positions and it not enabled to form anhydrides or the different substituents.

How can applicants obtain amides , amine , imino, carboxylic acid derivatives substituted at different positions when they are extracting and isolating the compound from ascidian. How can a compound with a Markush substitution be obtained from a natural product.?

The extraction procedures does not use all the various regents to even make these. The examples provided also do not have these substitution at 1, 4, 5 and 8. Thus it cannot be seen how these are enabled.. Applicants have in the claims modified compounds , which are obviously not isolated from ascidian.

Art Unit: 1625

The applicants have shown where they have support for the substitution at positions 1, 4, 5 and 8 however are on analogs not on the isolated compound. Thus isolating compounds which have these substituents is still considered as new matter.

The rejections are repeated here.

Applicants have amended the claims to insert different groups at 1, 4, 5 and 8 positions.

The previous rejection under 35 USC 112 first paragraph over enablement of solvates anhydrides, tautomers and salts still stands over claims 1, 11, 13, 14 and 20.

The specifications has one exaction process on pages 11 and 12 and uses a limited number of reagents. These reagents cannot form all the salts solvates and anhydrides.

Regarding solvates:- The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist.” The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

The rejection still stands.

Art Unit: 1625

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 11,13, 14, 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims have been amended to insert the optional substituents at 1, 4, 5, 8 to be halogen, amine, amino, imino, carboxylic acid or amide.

The specification do not have the written description for these substituents nor for them to be at the specific positions on compounds that are isolated from ascidian.. This changes the scope of the compounds and as such is new matter. The specifications lacks written description that these groups can be present at these various locations on compounds that are isolated. The applicants have shown where they have support for the substitution at positions 1,4,5 and 8 however are on analogs not on the isolated compound. Thus isolating compounds which have these substituents is still considered as new matter.

***Conclusion***

Claims 1, 2,11 , 13, 14, 20, 21, 23, 48-52 are rejected

Art Unit: 1625

Claims 3-10, 12, 15-10, 24-47 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/  
Primary Examiner, Art Unit 1625

June 2<sup>nd</sup>, 2009.